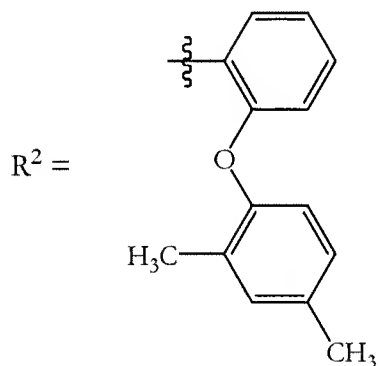


## REMARKS

Claims 1-13 are pending in the application. Claims 3, 4, 6, and 9 are amended to correct typographical errors in dependencies inadvertently introduced in the preliminary amendment filed on October 26, 2005. Support for these amendments can be found, for example, in the originally filed claims. Claim 11 is amended to recite the chemical structure of “abafungin.” No new matter is added. Support for this amendment can be found, for example, on pages 5 and 6 of the specification.

### **Rejection Under § 112, Second Paragraph**

The Office Action objects to the use of the trade mark “abafungin” in claim 11 as being indefinite. Claim 11 has been amended to specify that R<sup>1</sup> represents hydrogen and R<sup>2</sup> represents a substituent of the formula:



Thus, Applicant respectfully requests this rejection be withdrawn.

### **Rejections Under § 102(b)**

Claims 1-2, 7-9 and 11-13 stand rejected as allegedly anticipated by U.S. Patent No. 4,956,370 to Ippen et al. (“Ippen”). Applicant respectfully traverses these rejections.

To anticipate, the prior art reference must disclose each and every feature of the claimed invention (*Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631 (Fed. Cir. 1987)). Ippen does not disclose each and every feature recited in the claims. Ippen discloses a large

number of types of pharmaceutical formulations, namely tablets, coated tablets, capsules, pills, granules, suppositories, solutions, suspensions, emulsions, pastes, ointments, gels, creams, lotions, powders and sprays (col. 19, lines 62-66). However, Ippen is silent as to a “pharmaceutical, antimycotically active nail lacquer,” as is recited in claim 1.

The Office Action takes the position that the pharmaceutical composition described by Ippen is “able to be prepared in various forms are cable (sic) of being nail lacquer compositions.” However, even assuming for the sake of argument that Ippen discloses subject matter that is “capable of being” the claimed subject matter, this is not the legal standard for anticipation. Clearly, none of the pharmaceutical formulations disclosed by Ippen are a nail lacquer. Thus, Ippen fails to disclose each and every element of the pending claims. Therefore, Applicant respectfully requests that the rejection be withdrawn.

#### **Rejections Under § 103(a)**

Claims 1-6 and 10 are rejected as allegedly obvious over Ippen in view of U.S. Patent No. 6,224,887 to Samour (“Samour”) and/or U.S. Patent No. 6,719,986 to Wohlrab (“Wohlrab”). Applicant respectfully traverses these rejections.

In rejecting claims 1-2 under this section, the Office Action merely reiterates the anticipation rejections, arguing that Ippen “teaches all the limitations of instant claim 1” (Office Action, p. 6). However, as discussed above, Ippen is completely silent on nail lacquer. Although Ippen discloses that the “active compounds of the pharmaceutical preparations may be administered locally, orally, parenterally, intraperitoneally and/or rectally, preferably parenterally, in particular intravenously,” (col. 21 lines 29-32), none of these routes of administration are suggestive of a nail lacquer. Thus, claim 1 is neither anticipated by Ippen, nor obvious over Ippen.

Moreover, the pending claims are not obvious over Ippen in view of Samour or Wohlrab. On the basis of *KSR* and the Federal Circuit and District Court cases following *KSR*, the current standard of obviousness takes into account: (1) whether there would have been a “reason that would have prompted a person of ordinary skill in the relevant field to combine the elements in the way the claimed invention does;” and (2) whether the combination of elements would have

yielded “predictable results” *i.e.*, whether there would have been a reasonable expectation of success. (See *e.g.*, *PharmaStem* 491 F.3d at 1360 (“The burden falls on the patent challenger to show by clear and convincing evidence that a person of ordinary skill in the art would have had reason to attempt to make the composition or device, or carry out the claimed process, and would have had a reasonable expectation of success in doing so.”) (emphasis added, internal quotations omitted)).

Applicant submits that in the instant case, the Office Action provides no reason that would have prompted a person skilled in the art to combine the teachings of the cited references to arrive at the claimed nail lacquer, nor demonstrated that a person skilled in the art would have had a reasonable expectation of success fully making and using such a combination.

In this regard, Applicant first points out that Ippen discloses that compositions it discloses are preferably administered “parentally, in particular intravenously,” *e.g.*, using solutions or emulsions (col. 21, lines 31-32 and col. 20, lines 58-60). Particularly in view of Ippen’s complete silence on nail lacquers, one of skill in the art would not have reasonably expected that a composition that is preferably administered parentally or intravenously, *e.g.*, in the form of a solution or emulsion, would be successful if instead administered in the form of a pharmaceutical, antimycotically active nail lacquer. This is because, as well-known in the art, a compound that is systematically (*e.g.*, parenterally or intravenously) administered cannot be expected to yield the same pharmacological effect when it is topically administered, in particular as a nail lacquer. Despite this, Applicant recognized that the claimed substituted 2-aminothiazoles could effectively be administered in the form of a pharmaceutical, antimycotically active nail lacquer, and the efficacy of the claimed nail lacquer is demonstrated in the specification. See, *e.g.*, Example No. 1, which discloses complete cure of all cases of onychomycoses of the toenails within 100 to 150 days of the beginning of treatment with an embodiment of the claimed invention.

Samour and Wohlrab do not cure this defect. The Office Action merely cites Samour for its alleged disclosure of components recited in dependent claims. For example, the Office Action states that:

It would have been prima facie obvious to one of ordinary skill in the art at the time the claimed invention was made to modify the composition of Ippen et al...by incorporating permeation enhancing agent and polymeric film-forming agents as taught by Samour et al...., since the purpose of the permeation enhancing agent is for the penetration of various pharmacologically active principles like through the skin as extensively known and discussed in the art it renders it commonly used mechanism of permeation of pharmaceutical actives in a targeted part of the body. (Office Action, p. 7).

However, even assuming, purely for the sake of argument, that one of skill in the art would have been motivated to incorporate such agents of Samour into the tablets, coated tablets, capsules, pills, granules, suppositories, solutions, suspensions, emulsions, pastes, ointments, gels, creams, lotions, powders or sprays of Ippen, the result would not be a “pharmaceutical, antimycotically active nail lacquer,” as is recited in claim 1. Therefore, the combination of Ippen and Samour is simply insufficient to render the claimed nail lacquer obvious.

Wohlrab is cited for its alleged disclosure of hyaluronate lyase. Again, even if one of skill in the art would have been motivated to incorporate the hyaluronate lyase of Wohlrab into a composition produced by combining the tablets, coated tablets, capsules, pills, granules, suppositories, solutions, suspensions, emulsions, pastes, ointments, gels, creams, lotions, powders or sprays of Ippen with the agents of Samour, the result would not be a “pharmaceutical, antimycotically active nail lacquer,” as is recited in claim 1.

For at least the reasons given above, Applicant respectfully submits that the pending claims are not obvious over Ippen, alone or in view of Samour and/or Wohlrab. Applicants respectfully request these rejections be withdrawn.

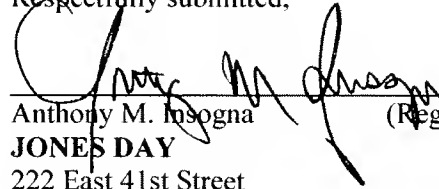
### **Conclusion**

In light of the above amendments and remarks, the Applicant respectfully requests that the Examiner reconsider this application with a view towards allowance. The Examiner is invited to call the undersigned, if a telephone call could help resolve any remaining items.

An extension of time for a period of three months, the fee for which will be paid via EFS-Web, is respectfully requested. No other fees are believed due at this time. However, please charge any required fees, or credit any overpayments, to Jones Day Deposit Account No. 50-3013.

Date: December 31, 2008

Respectfully submitted,



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